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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,175	03/16/2004	Meinrad Schienle	V0195.0010	4132

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EXAMINER	
CHONG, DAVID W	

ART UNIT	PAPER NUMBER
4151	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/803,175	SCHIENLE ET AL.	
	Examiner	Art Unit	
	DAVID CHONG	4151	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 June 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/23/04 and 6/29/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 36 recites the limitation "the second material" in line 2. There is insufficient antecedent basis for this limitation in the claim. It will be taken to depend on claim 33 which recites a "second material."

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 28-33, 35-41, 43, 45-48, 50-54 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,846,708 to Hollis et al.

4. For claim 28, Hollis et al. teach an apparatus for identifying molecular structures (i.e. a biosensor, see Abstract, lines 1-2) by using a semiconductor chip (col. 4, line 31) comprising a substrate (Abstract, line 3), at least one electromagnetic radiation detection device in or on the substrate (col. 9, line 1, Fig 15), an optical filter layer on the substrate (col. 9, lines 45-49, Fig. 15 filter 250 on substrate 212), an immobilization layer arranged on the optical filter layer and immobilizing capture molecules (col. 4, lines 34-36, Fig. 15 hybridized DNA) wherein the electromagnetic radiation detection device (Fig. 22, detector gate electrode 220), the optical filter layer (Fig. 22, filter 250),

and the immobilization layer (Fig. 22, capture molecules 22) are integrated in the fluorescence biosensor chip as shown by all of Figure 22.

5. For claim 29, the substrate is produced from silicon material (col. 8, line 66).

6. For claim 30, the electromagnetic radiation detection device has a photodiode arranged such that electromagnetic radiation of a first wavelength range is detected (col. 9, lines 41-44).

7. For claim 31 and 32, the optical filter layer reflects and/or absorbs electromagnetic radiation of a second wavelength range (col. 9, lines 50-53), at least part of the first wavelength range lying outside the second wavelength range. Hollis teaches that the filter blocks (cut-off filter) gamma particles (col. 9, line 50) which are outside the fluorescent range being detected but passes secondary emissions (bandpass filter).

8. For claims 33, 35 and 36, Hollis teaches a filter (col. 9, lines 45-47) which is formed in the dielectric layer therefore having a sequence of two layers. The first material having a high refractive index formed from an aluminum metal (col. 9, lines 45-47) such as aluminum oxide and a second material having a low refractive index such as silicon dioxide (col. 9, lines 20-22).

9. For claim 37, Hollis teaches that the immobilization layer has the material silicon dioxide or gold (col. 11, lines 46-49).

10. For claims 38 and 39, Hollis teaches a circuit layer arranged between the substrate and the optical filter layer and electrically coupled to the at least one electromagnetic radiation detection device wherein at least one electrical component is

integrated into the circuit layer (Figure 16, electrical component CCD gate 220 in between substrate 212 and filter 250). A charge is induced beneath the CCD gate (col. 8 line 67 to col. 9 line 3) which electrically drives the electromagnetic detection device 220.

11. For claim 40, 41 Hollis teaches a multiplicity of capture molecules coupled to the immobilization layer (col. 4, lines 34-37) wherein a DNA molecule that is to be detected and is complementary to the capture molecules can be coupled to each of the capture molecules (col. 6, lines 42-44).

12. For claim 43, Hollis teaches using a fluorescence marker (col. 9, line 7) that would absorb light at one wavelength range then emit light of a different range.

13. For claim 45 and 46, Hollis teaches an isolation trench (fig. 15, test well 218A) for optically isolating adjacent electromagnetic radiation detection device (Fig. 15, CCD gate 220) is introduced into at least one surface region of the fluorescence biosensor chip. The isolation trench extends through the immobilization layer into a region of the optical filter layer such that an electromagnetic radiation detection device is arranged below each region between each of two adjacent isolation trenches (Fig. 15, two test wells 218A and 218B with detectors 220 below each trench). The isolation trench is covered with a layer made of an absorbent material (hybridized DNA) wherein the absorbent material absorbs or reflects electromagnetic radiation at least of the first wavelength range (col. 9, lines 4-10).

14. For claim 47, Hollis teaches a barrier layer made of an absorbent material in at least one region of the circuit layer (dielectric or polymer layer, col. 9, line 20). An

electro magnetic radiation detection device is arranged below the barrier layers (Figure 15, detection devices 220 below the barrier layer 216). This barrier layer is capable of absorbing electromagnetic radiation of a respective wavelength range.

15. For claims 48 and 52, Hollis et al. teach an apparatus for identifying molecular structures (i.e. a biosensor, see Abstract, lines 1-2) by using a semiconductor chip (col. 4, line 31) and having a plurality of test sites (claim 11, line 3). The biosensor chip comprises a substrate (Abstract, line 3), at least one electromagnetic radiation detection device in or on the substrate fully capable of detecting radiation of a first wavelength range (col. 9, line 1, Fig 15), an optical filter layer on the substrate fully capable of reflecting electromagnetic radiation of a second wavelength range (col. 9, lines 45-49, Fig. 15 filter 250 on substrate 212), an immobilization layer arranged on the optical filter layer and immobilizing capture molecules (col. 4, lines 34-36, Fig. 15 hybridized DNA) wherein the electromagnetic radiation detection device (Fig. 22, detector gate electrode 220), the optical filter layer (Fig. 22, dotted line is the filter), and the immobilization layer (Fig. 22, capture molecules 22) are integrated in the fluorescence biosensor chip as shown by Figure 22. With regard to the limitation of claim 48 reciting "an electromagnetic radiation source irradiating a surface region", Hollis et. al teach that light photons are impinged on the test site. The filter reflects a second wavelength range which would be outside the first wavelength range.

16. For claim 50, Hollis teaches a multiplicity of capture molecules coupled to the immobilization layer (col. 4, lines 34-37) wherein a DNA molecule that is to be detected

and is complementary to the capture molecules can be coupled to each of the capture molecules (col. 6, lines 42-44).

17. For claim 51, Hollis teaches that the molecules to be detected are marked with a fluorescent dye that absorbs light at a specific wavelength and then emits it at a different wavelength.

18. For claim 53 and 54, a light source is fully capable of emitting light incident at a predeterminable angle with respect to the direction of the normal to the optical filter layer. It is also fully capable of emitting light in pulses which would be detected in time intervals between pulses by the detection device.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

21. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

22. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. Hollis et al. in view of U.S. Patent No. 4,827,118 to Shibata et al.

23. For claim 34, Hollis teaches the elements of claim 28 and 32. It does not teach that the cut-off filter is a color filter produced from an organic material. Shibata et al. teach a color filter made up of an organic material (col. 3, line 27) for use in spectroscopic measurement (col. 1, line 10). At the time of the invention it would have been obvious to a person of ordinary skill in the art to use the color filter taught by Shibata since it has improved light resistance (col. 3, line 10) which would protect the filter from deteriorating over time due to light exposure.

24. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,846,708 to Hollis et al. in view of U.S. Patent Pub. 2003/0054355 to Warthoe.

25. For claim 42, Hollis teaches the elements of claim 28 and 40. It does not teach that a surface section of the immobilization layer is free of capture molecules so that a

noise signal can be tapped off. Warthoe teaches a microsensor in which part of the sensor is free of capture molecules and is used as a reference cantilever (para. 0055, lines 14-15). The reference cantilever is used to subtract background drift or noise directly from the measurement (para. 55, last 3 lines). At the time of the invention it would have been obvious to a person of ordinary skill in the art to incorporate the teaching of Warthoe into the teaching of Hollis so that a reference a signal could be tapped off in order to reduce noise level. This would result in a more accurate measurement of samples due to a reduction in noise (para. 0055, lines 7-8).

26. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,846,708 to Hollis et al. in view of U.S. Patent No. 5,832,165 to Reichert et al.

27. For claim 44, Hollis teaches the elements of claim 28, 40 and 43. It does not teach that the fluorescence marker is selected from the given group of dyes. Reichert uses Cy5 as a fluorescent marker for the analysis of molecules immobilized on a biosensor (col. 9, lines 58-64). At the time of the invention it would have been obvious to a person of ordinary skill to utilize Cy5 since DNA labeled by Cy5 will emit a detectable fluorescent light when exposed to laser light.

28. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,846,708 to Hollis et al. in view of U.S. Patent No. 6,395,558 to Duveneck et al.

29. For claim 49, Hollis teaches the elements of claim 48. It does not teach that the electromagnetic radiation source is selected from the given group of sources.

Duveneck teaches an optical chemical sensor which utilizes a laser to excite samples labeled with luminescent dyes. At the time of the invention it would have been obvious to a person of ordinary skill to use a laser since it would irradiate a sample at the proper wavelength for fluorescence to occur in the teaching of Hollis.

Conclusion

30. FR2747785 was listed as particularly relevant in the international search report, however, it was not used for rejections since it did not contain the optical filter layer in claim 28 and claim 48 of the invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID CHONG whose telephone number is (571)270-3718. The examiner can normally be reached on Monday through Friday, 7:30 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Kornakov can be reached on 571-272-1303. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DC
/Michael Kornakov/
Supervisory Patent Examiner, Art Unit 4151